

REMARKS

Applicant would like to thank the Examiner, Cris Rodriguez, for the interview which occurred on June 13, 2002 between Applicants' representative, Kristi L. Davidson, and the Examiner. The Examiner has rejected claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Adair U.S. Patent No. 5,311,858. Claim 7 is indicated to be allowable.

Claim 1 has been amended to specify that the memory metal tube is monolithic and of single-piece construction, support for which may be found at page 6, lines 21-23 wherein the application recites that "the single-piece construction is far more simple than with conventional baskets made of separate pieces that have to be connected." Further support may be found at page 4, lines 16-19, wherein it is described that the slots of the memory metal tube may be made by such methods as "etching, spark erosion, water jet cutting, abrasive water jet cutting, laser cutting, or any mechanical means." FIGS. 1A-1D also clearly show a monolithic tube 11. One skilled in the art may appreciate that the term "monolithic" refers to a solid, single piece structure as opposed to one assembled from pre-formed parts. The medical instrument of the present invention comprises a monolithic structure wherein slots are cut or formed in a memory metal tube, such that a basket portion is formed integral and monolithic with the remainder of the tube, and then the slotted tube is heat set to achieve the memory effect and/or superelasticity of the instrument.

Adair discloses a flexible tube 24 having a stone removal basket 34 connected to one end. The stone removal basket 34 "includes a plurality of spaced outwardly bowed flexible members 36, connected at one end to the distal end of tube 24 and connected at the other end to a circular ring 38 which has a central opening 40, best seen in FIGS. 3 and 9." (col. 4, lines 8-13.)

As is described and shown in FIGS. 3 and 9 of the Adair patent, each member 36 is a separate piece that is connected at each end to another part of the device. Thus, Adair discloses a basket 34 of multiple-piece construction. By definition, a multi-piece structure is not monolithic. Claim 1 of the present invention, as amended herein, is directed to a medical instrument comprising at least one monolithic memory metal tube of single-piece construction. This monolithic structure is created by cutting away portions of a tube to form the slotted retrieval basket section. Adair does not teach or suggest a monolithic retrieval basket. The monolithic structure is more reliable than a multiple-piece construction, which would be subject to breakage at the connections. Moreover, the multiple-piece construction limits the size of the device due to the complexity of making the connections between the multiple pieces. In the Interview of June 13, 2002, the Examiner indicated that the amendment of claim 1 to recite the monolithic, single-piece construction overcomes the rejection over Adair, as Adair discloses a non-monolithic, multiple-piece construction, and thus, Applicants respectfully request that the rejection of claim 1 be withdrawn.

In the Office Action of February 27, 2002, the Examiner states that "Adair is moot to the kind of material that the tube and the slots are made of. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select a memory metal material for the tube, since the selection of a well-known material in the art of endeavor would have been a mere obvious design choice." To the contrary, the monolithic structures of the present invention are not feasible with all materials, but rather, require shape memory and/or superelastic materials, such as nickel-titanium alloys, to achieve the single-piece construction.

Cutting a monolithic structure from a conventional metal, such as stainless steel, would be very difficult with respect to shaping that structure into an expandable structure, like the retrieval basket. It is complicated to bend the struts to a basket shape and define the unstrained, expanded shape then. Very complicated tools would be needed and damage on the fine struts would easily occur.

Applicants recognized that by using a memory metal tube in the present invention, the production of a smooth basket is very easy and miniaturization is not an obstacle. Memory metal may be easily shape set by holding it in a restraining means and then giving it simple heat treatment for a few minutes. For a basket, this can be done by just pushing or pulling the distal and proximal ends of the basket section so far together that the struts automatically bend outward. Simple wire may be used for that purpose. The benefits of shape memory and/or superelastic materials were recognized by the Applicants and applied to retrieval baskets thereby enabling the formation of a monolithic retrieval basket. The selection of shape memory and/or superelastic materials is not a mere design choice. For this additional reason, Adair does not teach or suggest a memory metal tube of single-piece construction programmed for a memory effect and/or superelasticity, such that there is no *prima facie* case of obviousness for claim 1 as amended herein. Applicants therefore respectfully request that the rejection of claim 1 be withdrawn.

During the Interview of June 13, 2002, the Examiner noted the simplicity of the invention, for example, noting the statement on page 6, lines 21-23 of the application that "the single-piece construction is far more simple than with conventional baskets made of separate pieces that have to be connected." The Examiner seemed to suggest that the simplicity of the

instrument construction renders it obvious. While it is possible that Applicants' representative misunderstood the Examiner, Applicants nonetheless wish to address any suggestion that the invention was simple and therefore obvious. The outcome of Applicants invention is an instrument that is simple to manufacture in comparison to the multiple-piece constructions of the prior art. The simple nature of the instrument, i.e. it's monolithic, single-piece construction, is the essence of the invention, and what constitutes a significant contribution to the art, which contribution should be considered both novel and unobvious. Simplicity is not the antithesis of invention. For example, in *Sensonics Inc. v. Aerosonic Corp.*, the Federal Circuit stated that "simplicity does not establish obviousness; indeed, simplicity may represent a significant and unobvious advance over the complexity of prior devices." 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996). In *In re Oetiker*, the Federal Circuit stated that "[s]implicity is not inimical to patentability." 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992) (citing *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279, 60 U.S.P.Q. 386, 388 (1944) (simplicity of itself does not negative invention); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1572, 1 U.S.P.Q.2d 1593, 1600 (Fed. Cir.) (The patent system is not foreclosed to those who make simple inventions), *cert. denied*, 481 U.S. 1052 (1987)). In light of the plurality of cases addressing this topic, it seems clear that the simplicity of Applicants' claimed instrument should not be used as a basis for obviousness.

Additionally, while the outcome of Applicants' invention is a simple construction, arriving at the construction was not simple and obvious. Memory metals comprise a complex and relatively new alloy system whose properties and benefits are still being realized. The utilization of these materials to develop instruments, such as those used in the medical field, that

are superior to their predecessors is an advancement in technology that was not arrived at simply. There is no teaching or suggestion in the art to substitute memory metals for the stainless steel materials previously used for retrieval baskets, and no recognition that doing so would allow for monolithic, single-piece retrieval baskets. In accordance with the Federal Circuit decision of *In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999), the analysis of patentability under § 103 requires the “critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field” to avoid the “tempting but forbidden zone of hindsight.” *Id. at 1616-1617*. As the Federal Circuit recognized, “[c]lose adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one ‘to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.’” *Id. at 1617* (citing *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984)). The presently claimed invention is deceptively simple, thereby potentially enticing the application of hindsight. Applicants respectfully caution the Examiner from drawing on hindsight knowledge and using the invention as a template for its own reconstruction. Applicants respectfully assert that it has been established that the combination of references lacks the necessary suggestion, teaching or motivation. “Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.” *Id.* Because the Examiner bears the burden of establishing a case of *prima facie* obviousness, and that burden has not been met, as set forth

above, Applicants respectfully request that the rejection be withdrawn. Applicants respectfully request that the Examiner bear in mind the above discussion when considering the next action. A Notice of Allowance as to both claims 1 and 7 is believed to be in order, and is respectfully requested.


Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made." Also attached hereto is a clean copy of all claims now pending in this application.

In view of the foregoing amendments to the claims and remarks given herein, Applicants respectfully believe this case is in condition for allowance and respectfully request allowance of the pending claims. If the Examiner believes any detailed language of the claims requires further discussion, the Examiner is respectfully asked to telephone the undersigned attorney so that the matter may be promptly resolved. The Examiner's prompt attention to this matter is appreciated.

Applicants are of the opinion that no additional fee is due as a result of this amendment. If any charges or credits are necessary to complete this communication, please apply them to deposit account no. 23-3000.

Respectfully submitted,

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